

REMARKS

Claims 1-21 are active. Claims 1 – 22 are subject to restriction. Applicant elected the claims of Group II, claims 12 – 22, drawn to a method of correcting an imbalance between two muscles. Claims 1-11 are withdrawn from consideration. Claims 12-21 are rejected under 35 USC 103 as being unpatentable over Hurtado in view of Axelgaard.

Applicant traverses the rejection of claims 12-21. Claim 12 is directed to a method of correcting a bunion condition in a foot.

The Office action agrees that the references are foreign to correcting a bunion condition and then states it is obvious to apply electrical signals to the foot. No convincing line of reasoning is given with respect to what is claimed. The claim is not applying signals to the foot, which has numerous muscles, but to specific muscles. No reason is given as to why it is obvious to apply the signals as claimed to specific muscles. The Office Action is silent to this. This is not a proper basis for the rejection.

More importantly, the fallacy of the position of the Office Action is that it was not known in the medical field to one of ordinary skill in the art of podiatry that muscle unbalance is the cause of the bunion condition, and more further removed, which muscles. As conceded by the Office Action neither cited reference discusses the bunion condition as being caused by a muscle imbalance. This recognition of the cause of the problem is the basis that the claimed subject matter is patentable.

It is the recognition of the CAUSE OF A PROBLEM that gives rise to patentable subject matter. See MPEP 2141.02 stating “the claimed invention as a whole must be considered” and that “discovering the source/cause of a problem is part of the ‘as a whole’ inquiry.” “[A] patentable invention may lie in the discovery of the source of the problem even though the remedy may be obvious once the source of the problem is identified. This is part of the subject matter as a whole which should always be considered in determining obviousness of the invention under 35 U.S.C. §103.” (Citing case) The Office Action does not cite a single reference that discloses that the source of the bunion condition is due to muscle unbalance and if such unbalance does exist, which

muscles are involved. The references do not go so far. Thus the conclusion of the Office Action does not follow the precedent mandated by the MPEP.

Exhibit A is a copy of a text entitled "Family Health and Medical Encyclopedia, Reader's Digest," prepared in association with Dr. Benjamin F. Miller, associate professor, University of Pennsylvania, School of Medicine, copyright 1970. At pages 541- 542, this text states that a bunion is the painful deformity of the big toe caused by shoes that bend this toe inward toward the smaller toes, putting pressure upon the joint connecting the big toe with the foot. An illustration shows that the condition is corrected by surgery requiring a bone to be removed. This teaches away from what is claimed, the antithesis of obviousness.

Thus it was not recognized by the prestigious University of Pennsylvania medical staff that the bunion condition is a result of or could be the result of muscle unbalance as taught by the present inventor. This belies any conclusion that it would be obvious to one of ordinary skill to do what is claimed, since one of ordinary skill would not use electrical stimulation, but surgery to correct the bunion condition. The level of skill of a person of ordinary skill in the art is also presumed to be one who thinks along the line of conventional wisdom and is not one who undertakes to innovate, whether by patient, systematic research or extraordinary insights, it makes no difference which. Phillips Petroleum v. U.S. Steel, 6 USPQ 2d 1065 (D. Ct. Del. 1987). (Citing cases). The present claimed invention thus goes against the conventional wisdom of others of ordinary skill in the podiatry art and thus is not obvious to such persons.

Exh. B is a letter dated November 19, 2003 from Howard J. Hillstrom, Phd., associate professor and Director of the Gait Study Center at Temple University School of Podiatric Medicine stating that he met with the present inventor regarding the subject claimed invention. Dr. Hillstrom states that FES (functional electrical stimulation) has been used for a wide variety of applications including treating paralyzed individuals, for

pain management, for delivering pharmaceutical agents transdermally and so on. He further states that he has never seen any article or abstract that has applied electrical stimulation techniques for non-invasive treatment of hallux abductovalgus (HAV) or the bunion deformity. He expresses the opinion that the claimed treatment is novel.

Attached as Exh. C is the CV of Dr. Hillstrom. As a result of his work and experience as shown in Exh. C, he is very familiar with the pathological condition referred to as the bunion condition of the foot.

In view of the above, the references do not teach or suggest what is claimed.

Applicant's information disclosure cites a number of references purportedly dealing with bunion conditions. These merely provide mechanical mechanisms or devices to treat the symptoms and not the cause. Neither of the cited references by the Office Action or the cited IDS references discuss or disclose the cause of the bunion condition. Applying signals to the various muscles specified in the references does not suggest the cause of the bunion condition, much less which muscles, where and what value signals are needed, to correct the bunion condition, if at all possible based on then present knowledge of one of ordinary skill. The fact that certain signals useful for some other muscles or conditions may overlap with what is claimed does not make it obvious to one of ordinary skill as to the cause of the condition.

Axelgaard is only concerned with the spine and Hurtado is only concerned with the abdominal muscles. There is no support in the Axelgaard or Hurtado as to the cause of the bunion condition. The Office Action extrapolates unrelated problems and solutions to the claim 12 method. But those solutions to the unrelated problems do not in any way suggest the cause of the bunion condition or solutions as claimed. Applicant in his prior responses has shown that those disclosed solutions are not the same as what applicant discloses and thus will not in practice solve the bunion condition problem, much less teach the cause of the condition. That is applicant's contribution and not that of the

references. Applicant teaches the cause of the bunion condition and also what muscles to stimulate, and what signals to use for such stimulation. The references do not do this. For the reasons given, Claim 12 is believed allowable.

Claims 13-21 are directed to specific solutions directed to bunion correction and are believed allowable at least for the same reasons as claim 12. The cited references are even more remote to these claims and at best are only an invitation to proscribed experiment. What will work on one set of muscles is no indication that other muscles will respond similarly. These references do not go so far.

Claims 15 and 16 are also not specifically disclosed in the cited references. These dependent claims are believed further allowable for these additional reasons.

Since claims 12-21 have been shown to be in proper form for allowance, such action is respectfully requested.

Enclosed is a request for a two month extension of time to respond to the Office Action dated November 5, 2003 and a check in the amount of \$340 as the fee for this paper and the accompanying Notice of Appeal.

If any additional fee is due for this paper, the Commissioner is authorized to charge deposit account 03-0678 with respect to any underpayments or to credit that deposit account for any overpayments.

<u>FIRST CLASS CERTIFICATE</u>	
I hereby certify that this correspondence is being deposited today with the U.S. Postal Service as First Class Mail in an envelope addressed to:	
MS AF Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450	
 William Squire	April 5, 2004 Date

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Respectfully submitted,

Bassem M. Demian


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